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Daniel E. O'Toole, Clerk of Court
U.S. Court of Appeals for the Federal Circuit
Washington, DC 20439 (Via CM/ECF)

March 2, 2015

Re: *Teva Pharm. USA, Inc., et al. v. Sandoz Inc., et al.*, Nos. 2012-1567, -1568, -1569, -1570

Dear Admiral O'Toole:

Appellees (collectively "Teva") submit that three key factual findings compel affirmance of the District Court's decision that Teva's '808 patent is not indefinite. Following the Supreme Court's decision in this case, those findings, based on expert testimony, may be reviewed only for clear error. Fed. R. Civ. P. 52(a)(6); *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015). Because Defendants cannot seriously argue that those findings are clearly erroneous, this Court must construe the patent "in light of the facts as [the district judge] has found them." *Id.* at 841. The factual findings establish that to a skilled artisan, "average molecular weight" has a presumed meaning in this context, which means that the patent's specification resolves any ambiguity; that the presumed meaning is consistent with Figure 1 of the specification; and that the only statement causing ambiguity in the prosecution history was an error.

The Supreme Court held that in some cases, factual findings would be "close to dispositive of the ultimate legal question." *Id.* at 841-42. This is such a case: the facts established that the key claim term has a readily ascertainable meaning. And no intrinsic evidence defeats that definite meaning—not Figure 1, and not the prosecution history of later patents, which contains no clear and unambiguous disclaimer and cannot by itself override the specification or invalidate the patent. The District Court's decision that the patent is not indefinite should thus be affirmed.

The District Court's Findings and the Supreme Court's Decision Mandating Deference

The only remaining issue is whether Defendants have proven by clear and convincing evidence that the term "molecular weight" in the sole claim of the '808 patent is fatally indefinite even to an artisan with the necessary "very high" skill—a Ph.D. with "significant experience" in

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polypeptide synthesis. A66-68 (level of ordinary skill in the art). The District Court concluded that the claim is not indefinite, A303-18, A327, and construed it to mean peak average molecular weight (M_p), rather than one of the competing alternatives (number average (M_n) and weight average molecular weight (M_w)), *see* A304. That decision rested on three factual findings.

First, the District Court found that the “presumed meaning” of “molecular weight” would be “peak average” molecular weight, to a skilled artisan who was determining the average molecular weight of copolymer-1 using the method disclosed in the specification, *i.e.*, size exclusion chromatography (SEC) without additional calculations. A306; *see* A307. *Second*, the District Court found that the other relevant part of the specification, Figure 1, was consistent with the “peak average” construction, because a skilled artisan would expect the peak of the curve to shift when the data were transformed from a chromatogram into Figure 1. A308-09. *Third*, the District Court found that, of two statements Teva made to the PTO in prosecuting other patents after the ’808 patent issued, the first rested on an obvious scientific error. As a result, “a person of ordinary skill in the art would not rely on” that erroneous statement. A316.

Defendants appealed. In this Court’s prior decision, the panel reviewed all aspects of the claim construction *de novo*, as circuit precedent then required. 723 F.3d at 1368, 1369. The Court did not discuss the factual finding concerning the “presumed meaning” of molecular weight found using SEC, *or* the factual finding concerning the expected shift in Figure 1. And while it acknowledged Teva’s argument that one of the statements to the PTO was erroneous, *id.* at 1368, it did not discuss that error when analyzing the prosecution history. Instead, the Court concluded that Figure 1 “makes it difficult to conclude that M_p is the intended measure”; that the specification’s direction to use SEC technology sheds no light on the intended measure; and that Teva’s statements to the PTO “cannot be reconciled.” *Id.* at 1369.

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The U.S. Supreme Court vacated this Court's decision and remanded. The Supreme Court held that this Court must apply the clear-error standard set out in Fed. R. Civ. P. 52(a)(6) to the District Court's subsidiary factual findings. And although the ultimate question of construction is reviewed *de novo*, the patent must be interpreted "in light of the facts as [the district judge] has found them," unless the factual findings are set aside for clear error. *Teva*, 135 S. Ct. at 841. That is so even if resolving the factual dispute is "nearly dispositive" of the legal question of the claim's meaning. *Id.* at 841-42. Two key types of factual issues relevant to claim construction are "the background science" and "the meaning of a term in the relevant art." *Id.* at 841. The Court specifically held that the District Court's finding about the shift in Figure 1 "was a factual finding" that was binding on this Court unless it was clearly erroneous. *Id.* at 843.

During the Supreme Court proceedings, eight of the nine original patents-in-suit expired. *See* 723 F.3d at 1376 n.5. The '808 patent (which is not listed in the *Orange Book*) will expire September 1, 2015, 17 years from issuance. *See* A339. Despite their loss in the District Court, Defendants are not now enjoined from violating the '808 patent, because this Court's (now-vacated) mandate compelled the District Court to delete the injunction on the '808 patent from its original judgment. *Compare* 08-cv-7611 ECF No. 355 *with* A285-86. The District Court felt it could not restore the injunction until this Court acts on the remanded appeal. 2015 WL 585623 (S.D.N.Y. Feb. 10, 2015). Defendants, however, do not have FDA approval to market a product.

Applying The Correct Standard Of Review, This Court Should Affirm

By vacating and remanding for reconsideration of Defendants' appeal under the correct standard of review, the Supreme Court has required this Court to start anew, "seriously confronting" the significance of the Supreme Court's reasoning. *Cavazos v. Smith*, 132 S. Ct. 2, 7-8 (2011) (per curiam); *cf. ePlus, Inc. v. Lawson Software, Inc.*, 760 F.3d 1350, 1364 (Fed. Cir.

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2014) (vacatur requires the court on remand to “analyze . . . anew”). Under the correct analysis, the District Court’s findings compel the conclusion that Teva’s ’808 patent is not indefinite.

1. Defendants Bear A Substantial Burden: Teva’s patent is “presumed valid.” 35 U.S.C. § 282 (2006). Defendants therefore were required to establish the predicate facts—such as the absence of an established meaning to persons of skill in the art—by clear and convincing evidence. *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1345 (Fed. Cir. 2007). Their burden is heightened on appeal, where they “not only must overcome the clear error standard, but . . . must do so in the face of a presumption of [patent] validity.” *Commonwealth Scientific & Indus. Research Org. v. Buffalo Tech. (USA), Inc.*, 542 F.3d 1363, 1380 (Fed. Cir. 2008). Even under the Supreme Court’s most recent refinement of the indefiniteness standard, Defendants must do more than just show that their interpretation is reasonable. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128 (2014) (rejecting no-ambiguity standard). They must show that the patent, construed in light of the intrinsic evidence *and* the facts found by the District Court about the terminology and science in the patent, fails to inform a skilled artisan, with reasonable certainty, which measure of average molecular weight to use.¹

2. The District Court Did Not Clearly Err In Finding That The Key Term Has A Presumed Meaning In The Art: In the District Court, both parties submitted evidence on a key *factual* point: whether a skilled artisan would understand the use of SEC technology to identify M_p as the correct measure of average molecular weight. Defendants labored to convince the District Court that the answer was no—that the use of SEC would not point a skilled artisan to any one measure—but the Court found that Defendants had “fail[ed] to carry their burden” of proving this point by clear and convincing evidence. A311. Instead, the District Court found,

¹ *Nautilus* changed the verbal formulation of the test, but this Court has not hesitated to affirm pre-*Nautilus* decisions without feeling compelled to remand to apply that new formulation. *E.g.*, *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1259 (Fed. Cir. 2014).

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average molecular weight *would* have a “presumed meaning”—peak average—to a skilled artisan who knew that the molecular weight was to be determined by SEC, without performing additional calculations. A306; *see* A307, 312.² That finding about “the meaning of a term in the relevant art” is plainly factual. *Teva*, 135 S. Ct. at 841.

The finding also has ample support in the record. In the District Court, *Teva* proved through extrinsic evidence that *only* peak average may be obtained directly from the calibrated chromatogram. A7085 ¶¶ 42-43; A7097-98 ¶ 70; A8946 ¶ 6. Determining number average or weight average requires “further data manipulation and calculation.” *Id.*; *see* Proposed Supplemental Appendix (*to be jointly submitted after the parties exchange letter briefs*) (“SA”) 2098 (the chromatogram “does not give you these values directly”). (Notably, both sides’ experts calculated M_w from Figure 1 and reached widely divergent answers. *Compare* SA9704 ¶ 23 *tbl.3 with* A5825.) And because the ratio of M_w to M_n is significant to chemists, “it is common practice for those two averages to be listed together when referencing data generated by SEC”; by contrast, “[i]t is uncommon . . . for only one of M_n or M_w to be listed” in that context. SA7100 ¶ 75.³ The claim here plainly calls for a single average, not a pair or a ratio.

Despite the District Court’s findings, Defendants have continued to insist on appeal that the use of SEC does not resolve which measure of average molecular weight to use—that because the SEC technology *can* produce M_p , M_w , and M_n , one should infer that a skilled artisan would consider them all *equally likely* outputs of SEC. Previously, on *de novo* review, this Court agreed with Defendants that “[t]he specification does not resolve the ambiguity” because “SEC does not *exclusively* provide M_p .” 723 F.3d at 1369 (emphasis added). That argument is

² If the skilled artisan were asked to use a different method than SEC, the presumed meaning would be different. *E.g.*, SA7081 ¶ 38 (osmometry yields number average).

³ Any and all of this evidence is a proper basis to sustain the District Court’s findings, whether or not it is expressly cited in the decision. *E.g.*, *Gaylord v. United States*, __ F.3d __, __, 2015 WL 449192, at *4 (Fed. Cir. Feb. 4, 2015).

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incompatible with the District Court's finding and the supporting facts; it certainly cannot survive the clear-error review the Supreme Court has now mandated.

This Court must construe the patent "in light of" the factual findings that are not clearly erroneous. The District Court expressly rejected the argument that all three measurements were equally likely outputs; to the contrary, it found that a skilled artisan would be able to discern that M_p was the correct measurement. Under Rule 52(a)(6) and *Teva*, that factual inference is the District Court's to make, subject only to clear-error review. *See Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985) (deferential clear-error review applies even to findings based on "inferences from other facts"); *Pillsbury Co. v. United States*, 431 F.3d 1377, 1380 (Fed. Cir. 2005) (reviewing trial court's factual inference, even from *undisputed* facts, only for clear error); *see also Teva*, 135 S. Ct. at 838-39 (pointing out the district court's comparative advantage in factfinding). And Defendants never tried to identify clear error in that finding.

In fact, there is *no* evidentiary support for Defendants' position that that M_n , M_w , and M_p were all equally plausible; Defendants certainly cannot overcome *both* the clear-and-convincing standard *and* Rule 52(a)(6). While Defendants presented multiple expert declarations on this issue, their experts never attempted to dispute the point that peak average was the only figure that could be read *directly* from a chromatogram prepared using SEC. They acknowledged that deriving number average or weight average requires additional calculations. *E.g.*, SA2098 (SEC "does not give you these values directly"); SA9698-99 ¶ 14. Defendants' expert instead focused on *ruling out* peak average as a plausible meaning, on two grounds: that Figure 1 forecloses the use of peak average, and that peak average is not truly an average. SA7769-70 ¶¶ 41-42; SA9699-700 ¶¶ 16-17. The former ground is no longer viable in light of the Supreme Court's ruling; Defendants have abandoned the latter ground and conceded that peak average is a

plausible meaning of average molecular weight in this context. Sandoz Opening Br. 31, 35.

They are left with nothing but their insistence that all three measures are equally likely. The District Court properly found to the contrary. That finding is controlling on appeal.

3. The Finding Of Presumed Meaning Was A Factual Finding: Even though both sides submitted expert evidence on the presumed meaning of average molecular weight in the District Court, Defendants now argue that the District Court’s finding is purely legal and entitled to no deference. But the Supreme Court has made clear that “the meaning of a term in the relevant art” to skilled artisans is a factual question. *Teva*, 135 S. Ct. at 841. Defendants’ position appears to be that because the finding referred to the meaning of the scientific term “in the context of the patents-in-suit,” the District Court somehow crossed the line into legal interpretation. That argument is flatly incorrect.

Defendants would absurdly read the Supreme Court to have held that specialized meaning *in the abstract* is factual, but specialized meaning *in the relevant context* is legal. The Court held no such thing, and no precedent would support such an arbitrary distinction. When a term has different meanings in different contexts (as “average molecular weight” does, *e.g.*, A8946 ¶ 6), the only testimony relevant to claim construction is testimony about the meaning in contexts like the one in the patent. *See, e.g., Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002) (remanding for “any appropriate recourse to extrinsic evidence concerning the usage and understanding of [a] term . . . *in relevant context*” (emphasis added)). To render a relevant opinion on the meaning of the word “nucleus” among skilled artisans, for example, an expert would have to know whether the context of the patent is atomic or cellular. The expert’s testimony that there is a specialized meaning in that context is factual, because it is “data necessary to the comprehension of the language of the patent.” *Teva*, 135 S. Ct. at 841 (quoting

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2 W. Robinson, *Law of Patents* § 732, at 482-83 (1890) (intervening citation omitted)). It is not an attempt to construe the patent, *e.g.*, to apply legal canons of claim construction.

That is the case here. Dr. Grant made clear that his references to “context” were simply aimed at aligning his testimony with the issue before the court: “In the absence of an identification of the method, it is true that ‘average’ could refer to more than one type of average. But in the context of the patents-in-suit,” *i.e.*, *using SEC without additional calculations*, “it is my opinion that peak average molecular weight would be understood to be the meaning of ‘average molecular weight’ if the type of average is not specified.” A8946 ¶ 6.

Defendants have fixated on the heading “Claim Construction” in Dr. Grant’s declaration (A7092), while ignoring what comes immediately after it: Dr. Grant explains that he is opining as to “the proper interpretation of *phrases or terms* . . . by the person of ordinary skill in the art.” *Id.* ¶ 54 (emphasis added).⁴ In other words, Dr. Grant’s evidence went to the meaning of disputed terms of art to the pertinent scientific audience in the relevant context. A8946 ¶ 6. He was not engaged in document construction. Indeed, the District Court expressly recognized that Dr. Grant was merely shedding light on the “technology” and “technical aspects of the patent.” A307 (citation omitted).

The Supreme Court’s treatment of Figure 1 forecloses any argument that just because an expert considers the scientific meaning of terms as they are used in the patent, he is testifying about document construction (legal) rather than science or terminology (factual). Figure 1 is, of course, part of the patent. Yet understanding what it means entailed factfinding, not pure law as Defendants have argued. The parties hotly disputed whether Figure 1 is consistent with Teva’s construction or instead rules it out. So the experts testified extensively about whether a skilled

⁴ Even if the “Claim Construction” heading somehow tainted what came after it, key parts of his evidence come from the earlier “Background” section that Defendants have conceded is factual. A7071 ¶ 22; A7085 ¶¶ 42-43.

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artisan would expect the peak of Figure 1 to differ modestly from M_p , the peak of the chromatogram. The District Court found that the shift *would* be expected—citing testimony in the “Claim Construction” section of Dr. Grant’s declaration, *see* A313 (citing A1016-17 ¶ 62). And the Supreme Court squarely held that “[t]he District Court’s finding about this matter was a *factual* finding—about how a skilled artisan would understand the way in which a curve created from chromatogram data reflects molecular weights.” *Teva*, 135 S. Ct. at 843 (emphasis added). That Supreme Court holding squarely refutes Defendants’ argument that this Court should once again review the “presumed meaning” finding *de novo*.

The same principles apply in contract interpretation, a context to which the Supreme Court expressly analogized. *Teva*, 135 S. Ct. at 837-38, 840. Although experts cannot opine on the ultimate meaning of the document, courts may take extrinsic evidence and find facts on the meaning of particular *terms*, including the specialized meaning applicable *to the document in question*. *See, e.g., Gjerlov v. Schuyler Labs., Inc.*, 131 F.3d 1016, 1020 (Fed. Cir. 1997) (reviewing for clear error when extrinsic evidence of the meaning of a particular scientific term as used in an agreement was dispositive, applying Rule 52(a) and state contract law).

After the District Court made its finding about the “presumed meaning” of average molecular weight in this context, the ’808 patent had to be interpreted “in light of the facts as [the district judge] ha[d] found them.” *Teva*, 135 S. Ct. at 841. The patent made no reference to performing the type of calculations necessary to find weight or number average using SEC. Nor was there anything in the claims or the specification to refute the presumed meaning, such as a definition adopted by the patentee acting as his own lexicographer or an applicable canon of claim construction. Accordingly, in this case, once the court made the finding of presumed meaning, there was only one conclusion to be drawn: that “a skilled artisan *would* ascribe that same

meaning to [the relevant] term in the context of the specific patent claim under review.” *Id.*; *cf. Gjerlov*, 131 F.3d at 1020. This is one of the cases the Supreme Court foresaw—cases in which the factual finding about a term’s meaning is “nearly dispositive” of “the ultimate legal question of the proper meaning of the term in the context of the patent.” *Teva*, 135 S. Ct. at 841-42.

4. The Supreme Court Has Made Clear That Defendants’ Argument Based On Figure 1 Was Inconsistent With The District Court’s Factual Findings: Throughout the proceedings, Defendants have argued that Figure 1 is proof “that Teva could not be right.” *Teva*, 135 S. Ct. at 842 (citing A312-13). This Court accepted that argument, holding that because the peak of the curve in Figure 1 was not at 7.7 kDa, it was “difficult to conclude that M_p is the intended measure.” 723 F.3d at 1369. The Supreme Court has now made clear that such a conclusion was inconsistent with the District Court’s factual findings about how a person with the very high level of skill in the relevant art would understand the likely shift in the peak of Figure 1. *Teva*, 135 S. Ct. at 843. Those findings are amply supported by Dr. Grant’s explanation that M_p is the peak of the chromatogram, *not* of Figure 1, and that transforming a chromatogram into a distribution curve like Figure 1 would cause the peak to shift. A7085-92. Thus, it is now settled that Teva’s interpretation—peak average—is consistent with Figure 1.⁵

Accordingly, construing the claim in light of the specification, a skilled artisan would conclude that average molecular weight must be determined directly by using SEC without further calculations; that the presumed meaning is therefore peak average; and that that meaning is consistent with Figure 1. Defendants’ attempt to defeat reasonable certainty by clear and convincing evidence founders right there.

⁵ Whether the weight average value is *also* close to the 7.7 kDa value in Figure 1, as Defendants have argued (*see* 723 F.3d at 1369), is irrelevant; the point is that Figure 1 does not *refute* the peak-average interpretation. Defendants’ argument in any event cannot be reconciled with their own expert’s calculation of M_w as 12.9 kDa (SA9704 ¶ 23 tbl.3), and this Court should not attempt to resolve the factual dispute on that point for the first time on appeal.

5. Defendants Cannot Prevail Based On Conflicting Prosecution History From Years

After The Patent Issued: The prosecution history does not defeat the reasonable certainty that the specification provides. This Court previously noted what it saw as a contradiction in the prosecution history, but it did not hold that contradictory prosecution history could trump the specification—nor would such a holding have been consistent with precedent. Rather, Defendants argued the prosecution-history issue (and this Court thus decided it) based on the premise that the specification either was silent or favored Defendants. *E.g.*, Sandoz Reply Br. 11 (skilled artisan would rely on prosecution history statement that “[id] not contradict the claims or specification”). But this Court must reevaluate that issue “in light of the facts as [the District Court] has found them,” *Teva*, 135 S. Ct. at 841. Under those findings, the specification points a skilled artisan to M_p . And under the *undisputed* facts, the one dissonant piece of prosecution history was baldly erroneous; the District Court found as a fact that the error was so apparent that no skilled artisan would rely on it. A316. In its prior decision, this Court noted the argument but did not address the finding. But the finding establishes that a skilled artisan reading both statements would not rely on the earlier, incorrect statement. The later statement—in which Teva expressly told the PTO that molecular weight meant *peak* average—banishes any shadow of indefiniteness. A310 (citing A3258). For all these reasons, discussed further below, the prosecution history does not help Defendants here.

First, the discussion above establishes that the specification resolves any ambiguity in the claims. Defendants cannot defeat that conclusion by pointing to prosecution history that they themselves claim is *ambiguous*. Sandoz Opening Br. 31; *see, e.g., AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1381-82 (Fed. Cir. 2005) (declining to rely on “ambiguous” prosecution history where “the teachings of the specification” resolved a claim term’s meaning).

Second, the only remaining patent-in-suit issued *six years* before Defendants allege that a conflict arose in the prosecution history (and four years before the first of the two statements was made). *See* A339, A3227, A3249. If the '808 patent was definite when it issued and for its first six years of existence, it remains definite today. We are aware of no case in which this Court has ever relied on subsequent prosecution history, from a different patent, to show the indefiniteness of a prior patent. Rather, subsequent prosecution history is at most an interpretive aid. *See, e.g., Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349-50 (Fed. Cir. 2004) (subsequent prosecution history “confirm[ed]” what specification already said). Indeed, it is far from clear that circuit law permits even an *express, uncontradicted disclaimer* to bind the patentee in the interpretation of an earlier patent.⁶ And here there is no express disclaimer, as discussed below.

Third, the mere existence of conflicting statements in prosecution history has never been a sufficient basis for *invalidating* a patent. This Court has long recognized that “because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). Prosecution history always presents “the potential for . . . ambiguities.” *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1372 (Fed. Cir. 2007). Thus, for instance, this Court stated in its previous opinion that the two statements here “cannot be reconciled.” 723 F.3d at 1369. But even “irreconcilable” statements do not make a patent

⁶ Compare, *e.g., Microsoft*, 357 F.3d at 1350 (citing *Ga.-Pac. Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1333 (Fed. Cir. 1999), for the proposition that a patentee cannot be “bound, or estopped, by a statement made in connection with a later application on which the examiner of the first application could not have relied”), with *Verizon Servs. v. Vonage Holdings*, 503 F.3d at 1307 (Fed. Cir. 2007) (applying a disclaimer to an earlier patent without acknowledging *Ga.-Pac. Corp.*); see also *Ateliers de la Haute-Garonne v. Broetje Automation USA Inc.*, 717 F.3d 1351, 1358 n.3 (Fed. Cir. 2013) (explaining that if there is a conflict between panel decisions, “the earlier panel decision controls”).

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indefinite: for instance, in *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573 (Fed. Cir. 1996), the prosecution history contained two statements this Court deemed “irreconcilable,” but that did not lead this Court to accept the indefiniteness defense. *Id.* at 1580. Rather, this Court simply held that the prosecution history was “unhelpful as an interpretive resource.” *Id.*

Fourth, unlike in many other cases with conflicting statements, in this case a person of skill in the art could readily tell on which of the two statements to rely. When it is “apparent to the interested reader,” *i.e.*, a skilled artisan, “that an error was made, . . . it would be unfair to enforce the error.” *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1348 (Fed. Cir. 2001); *Teva Br. 52*. Here, Defendants have conceded at every level, and the District Court expressly found, that the first statement was based on an obvious mistake. The first statement said that the answer must be “weight average molecular weight” because of the use of “kilodalton units,” A3229. But as any skilled artisan would know, *every* measure of molecular weight uses kilodalton units. A316, A1017-18 ¶ 64, A1229 ¶ 33. The answer was thus as facially incorrect as answering the question “Fahrenheit or Celsius?” with “Celsius, *because it is expressed in degrees.*” Although the error is enough to defeat reliance on the first statement, here there is more: the second statement gave the correct answer, *i.e.*, peak average molecular weight. Anyone using the subsequent prosecution history to construe the ’808 patent would read the *entire* history and see the correct statement supersede the incorrect one. Moreover, as shown above, the “weight average” statement is inconsistent with the teaching of the specification, making it even less likely to confuse a skilled artisan. On facts like those, this Court has consistently declined to allow an earlier, erroneous statement to override a later, correct statement. *See Elbex*, 508 F.3d at 1371-73; *AMP Inc. v. Burndy Corp.*, 871 F.2d 1097 (Fed. Cir. 1989) (unpublished) (“To the extent statements made during the earlier phases of the

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prosecution history might contradict the later prosecution history and the issued specification and claim language, the language of the latter prevails here.”).

Fifth, Defendants have tried to escape the consequences of the District Court’s finding—that the first statement is so erroneous a skilled artisan would disregard it—by arguing that *no matter how obviously incorrect the expressed reason*, Teva should be bound by its statement as a matter of law. This Court rejected exactly this argument in *Biotec*, a case with a far less obvious error. *See* 249 F.3d at 1348. And the argument incorrectly seeks to rely on the concept of prosecution disclaimer, *see* Sandoz Reply Br. 11 (citing disclaimer caselaw), which does nothing to advance Defendants’ indefiniteness argument. If the analysis stopped when Teva made the incorrect statement about weight average molecular weight, *that would make the claim definite, not indefinite*.⁷ Rather, Defendants would need to show that the *combination* of the two statements somehow works a disclaimer. But disclaimers must be “clear and unambiguous,” read in the context of the prosecution history “as a whole.” *Elbex*, 508 F.3d at 1371-72; *see also Cordis Corp. v. Bos. Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009) (“[U]nclear prosecution history cannot be used to limit claims.”). Conflicting statements are the very *opposite* of a clear and unambiguous disclaimer. *See Elbex*, 508 F.3d at 1372 (contradictory statements in same document provided further indication that earlier statement “was not a clear and unmistakable surrender,” especially where earlier statement was unsupported by specification).

By contrast, in disclaimer cases like *Springs Window Fashions LP v. Novo Industries, L.P.*, 323 F.3d 989 (Fed. Cir. 2003), *cited in* Sandoz Reply Br. 11, the patentee had evidently made no such mistake in prosecution—the prosecution-history statements were (1) *consistent*, (2) *repeated*, and (3) *not facially erroneous*. *See id.* at 996 (“[T]here is no indication that the

⁷ Defendants have not preserved any argument that the correct claim construction is “weight average” and that they do not infringe; this Court has already disposed of all of Defendants’ other arguments, including noninfringement, and Defendants did not cross-petition for certiorari.

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[disavowal] was simply an inadvertent misstatement The statements . . . were detailed, consistent, and repeated.”). Neither *Springs Window* nor any other case has applied Defendants’ desired “you said it, you’re stuck with it” reasoning to a single statement, with an obvious error, that the patentee subsequently contradicted with a *correct* statement that is consistent with the patent specification.

As shown above, for numerous reasons the prosecution history does not add any weight to Defendants’ indefiniteness claim. But if the Court reaches the question, under this Court’s cases, the District Court’s *uncontroverted* finding of error means that Defendants cannot invalidate the patent based on a mistake that would not have misled any skilled artisan.

* * * *

Defendants had to convince the District Court, by clear and convincing evidence, that the term “molecular weight” does not “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 134 S. Ct. at 2129. Even under the *Nautilus* standard, they failed to carry that burden: the District Court weighed their evidence but found that the term *does* have a presumed meaning—peak average—when SEC technology is used without additional calculations. The District Court’s view of the evidence is eminently “plausible in light of the record,” *Anderson*, 470 U.S. at 573-74. Consistent with the Supreme Court’s decision, this Court must now “interpret the patent claim in light of the facts as [the District Court] has found them.” *Teva*, 135 S. Ct. at 841. Here there is only one conclusion consistent with those findings: the claim term has a definite meaning to skilled artisans.

All parties agreed in a joint submission that a new oral argument on the remanded issues is warranted, and should be scheduled as soon as practicable following supplemental briefing. ECF No. 135 (filed Feb. 20, 2015). That remains Teva’s position.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the United States Court of Appeals for the Federal Circuit using the appellate CM/ECF system on March 2, 2015.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: March 2, 2015

/s/ William M. Jay
